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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,388	07/20/2001	Lawrence L. Kunz	295.003US5	1690

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	**PAPER NUMBER**
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/910,388	KUNZ, LAWRENCE L.	
	Examiner	Art Unit	
	Hope A. Robinson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/29/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/16/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

2 Applicant's response to the Office Action mailed March 17, 2006 on September 18, 2006 is acknowledged.

Claim Disposition

3. Claims 50-55 are pending and are under examination.

Information Disclosure Statement

4. The Information Disclosure Statements filed have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action. Note that several references have been lined through as they represent improper citations. Applicant is urged to resubmit the 1449 form.

Maintained-Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 50-55 remain rejected under 35 U.S.C. ə 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a method for reducing restenosis comprising administering a therapeutic agent that inhibits vascular smooth muscle cell migration and the claims read on a genus of inhibitors not adequately described in the instant specification. On page 5 of the instant specification therapeutic agents such as taxol, or taxotere, or protein kinases are disclosed, however, the claims broadly reads on any "therapeutic agents" which encompasses inhibitors not contemplated or described by the claimed invention. The claims encompass a large genus of inhibitors not adequately described. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. The specification fails to provide any additional representative species of the claimed genus, to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are

representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).* Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

6. Claims 50-55 remain rejected under 35 U.S.C. ɜ 112, first paragraph, scope of enablement, because the specification, while being enabling for a method of reducing restenosis by administering taxol, does not reasonably provide enablement for any therapeutic agent/inhibitor employed by the method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988)*. The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass a genus of inhibitors not supported by the instant specification. The specification on page 5 provides a discussion of therapeutic agents to be used as inhibitors of vascular smooth muscle cell migration such as taxol. Taxol is know in the art to inhibit neointimal smooth muscle cell accumulation after angioplasty (see Sollott et al., The Journal of Clinical Investigation, vol. 95, April 1995, pages 1869-1876), however, the claimed invention is not limited to taxol as it encompasses any

therapeutic agent. The specification also discloses therapeutic agents such as protein kinases and taxol analogs and provides examples such as "staurosporin and taxotere, however, the claims are not limited to the inhibitors disclosed. Undue experimentation would be required to test all possible inhibitors to determine if they have the desired activity.

No guidance is presented with regard to other members of the genus encompassed in the claims. One of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed inhibitors. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to construct all inhibitors of the claimed invention and examine the same for function.

The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those

skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).*

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test all possible inhibitors of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible inhibitors to find one that functions as described is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Ringel et al. (JNCI, 1991, vol. 83 (4), pages 288-291).

Ringel et al. disclose a new semisynthetic analogue of taxol (taxotere:RP 56976), which is disclosed as more potent than taxol in inhibiting cell replication. As the method only requires one step, which is administration of a therapeutic agent to reduce restenosis, the administration of taxotere would produce said result. In addition, the reference indicates that this compound is an analogue of taxol, which produces the claimed effect and also indicates that the analog is more effective than taxol, thus claim 51 is not anticipated.

8. Claims 50-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Bissery et al. (Cancer Research, 1991, vol. 51, pages 4845-4852).

Bissery et al. disclose the administration of Taxotere to patients and the effect of tumor growth inhibition. The reference discloses the use of a therapeutic amount that produced a good spectrum of efficacy. Claims reciting the specific vascular surgical procedure are also anticipated because the administration of the compound is the critical step, which would produce the resultant effect of growth inhibition with any surgical procedure. Further, administration was two fold more effective, thus direct. Therefore, the limitations of the claims are anticipated by the reference.

Response to Applicant's Arguments:

9. Applicant's arguments have been fully considered and the obvious-type double patenting rejections of record have been withdrawn with the filing of a terminal disclaimer. However, note that the rejection under 35 U.S.C. 112 first paragraph remains. Applicant states that the instant specification provides several therapeutic agents. The specification on many occasions makes mention of exemplary agents and the art provides in examples agents such as taxotere and cytochalasin B. However, the written description rejection remains because the art cannot replace the missing description and the instant specification is exemplary not limiting. The art does provide an enabling disclosure for the compounds mentioned, however, the broad scope of the claims encompasses more therapeutic agents than are mentioned in the specification or demonstrated in the art. Thus, the rejections of record remain. Note that new grounds of rejections have been instituted under 35 U.S.C. 102(b) for the reasons stated above.

Conclusion

10. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS
Primary Examiner 3/23/07

HOPE ROBINSON
PRIMARY EXAMINER